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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,826	03/30/2004	Theoharis C. Theoharides	51275/148	3055

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WILMERHALE/BOSTON
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BOSTON, MA 02109

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
10/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/811,826	THEOHARIDES, THEOHARIS C.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/08 has been entered.

Claims 40-45 remain pending in this application for Patent.

Claims 40-45 were examined on their merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40 and 42 are provisionally rejected on the ground of nonstatutory double patenting over claim 42 of copending Application No. 10/811,839, claims 14, 16, 18, 20, 25, 31 and 36 of copending Application No. 10/811,838, claims 14, 20, 25, 31 and 36 of copending application No. 10/610,909 and claims 14, 20, 25, 31 and 36 of copending application No. 10/439,301.

Claim 42 of 10/811,839 describes a composition comprising chondroitin sulfate, quercetin or myricetin, hydroxyzine and olive kernel extract (OKE) with the particular amounts of chondroitin sulfate and OKE as recited in Instant claim 42. Therefore, claim 42 of '839 'anticipates' claims 40 and 42 of the Instant application.

Claims 14, 16, 18, 20, 25, 31 and 36 of 10/811,838 describe a composition comprising chondroitin sulfate, quercetin or myricetin, hydroxyzine and OKE. Claim 32 of '838 for example, clearly discloses amounts of chondroitin sulfate and OKE which fall completely within the scope of the Instantly claimed amounts. Therefore, claims 14, 16, 18, 20, 25, 31 and 36 'anticipate' and claim 40 'makes obvious' claim 42 of the Instant application.

Claims 14, 20, 25, 31 and 36 of 10/610,909 describe a composition comprising chondroitin sulfate, quercetin or myricetin and hydroxyzine and OKE. Claim 36 specifically discloses the use of 200mg of chondroitin sulfate. Although none of the claims specifically recite the amount of OKE as Instantly claimed, varying amounts

of components in pharmaceutical compositions was well known in the art. One of ordinary skill in the art would have been motivated to modify the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment. Such variations in amounts of pharmaceutically active ingredients is considered optimization of result effective variables, conventional practice in the art of pharmacology.

Claims 14, 20, 25, 31 and 36 of 10/439,301 describe a composition comprising chondroitin sulfate, quercetin or myricetin and hydroxyzine and OKE. Claims 25, 31 and 36 of '301 specifically recite amounts of OKE and chondroitin sulfate which overlap or touch the ranges as Instantly claimed. Therefore, claims 14, 20, 25, 31 and 36 of 10/439,301 'anticipate' Instant claim 40 and 'make obvious' Instant claim 42.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 43-45 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44 and 45 recite 'against brain inflammatory processes'. This statement is considered vague in that the processes included in the brain inflammatory process are vast and many are unknown. It is unclear which processes Applicant is refering to. Due to this lack of clarity, one of ordinary skill in the art could not ascertain if they were in possession of the invention. It is suggested, based upon the teachings of the Instant specification, that this phrase be reworded to read 'against brain inflammation'. Thus, it is clear that what is being protected is the effect; or the inflammation, rather than some unknown biochemical mechanism thereof.

Claims 41 and 43 both recite the injection of interferon-β. These claims are indefinite because they fail to limit the claims they depend upon. It is clear that interferon- β is not part of the composition and thus these claims are improper. A suggestion to rewrite claims to include the interferon- β is to recite a kit wherein one part is the orally-administered composition, and a second part includes an inject able amount of interferon- β.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-45 rejected under 35 U.S.C. 102(b) as being anticipated by Theoharides (WO 02/060393 A2).

Theoharides (WO 02/060393 A2) discloses multiple compositions for treating inflammatory disorders such as multiple sclerosis (see entire WO document including the claims and Table 1). For treating these inflammatory conditions, Theoharides explicitly discloses several medicaments, including a composition comprising 50 mg chondroitin sulfate, 400 mg quercetin and 50 mg hydroxyzine, optionally in combination with interferon beta (see Example 10, p. 13).

Hence, Theoharides anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ronca et al. (1998) in view of Scott et al. (1987) in view of Gelber et al. (US 6, 576, 267 B2) in view of Noblie et al. (US 4, 265, 823) (in light of Dr. Duke's Phytochemical and Ethnobotanical Database*) and in view of Weiner et al. (US 2002/0009448 A1).

Ronca et al. (1998) studied some biochemical mechanisms of the well-known anti-inflammatory activity of chondroitin sulfate (see Abstract, Intro, Table 1, Table III and Table IV for example).

Ronca et al. did not propose a composition comprising chondroitin sulfate along with quercetin and/or myricetin and hydroxyzine, optionally an olive kernel extract or the injection of interferon-β.

Scott et al. (1987) disclosed that hydroxyzine was a non-steroidal anti-inflammatory agent (see Abstract).

Gelber et al. (US 6,576,267 B2) disclosed that quercetin was an effective anti-inflammatory agent (see col. 5, lines 64-66).

Noblie et al. (US 4, 265, 823) disclosed that estrole is a steroid which displayed anti-inflammatory properties (col. 10, lines 20-37). The claims state 'olive kernel extract'. Giving the phrase its broadest interpretation within reason, lacking any specific definition in the Instant specification, it is deemed that an 'olive kernel extract' may be a crude extract, or an isolated phytochemical from the olive kernel (seed). Estrole is a compound endogenous to olive kernel (see for example, Dr. Duke's Phytochemical and Ethnobotanical Database*, page 2 of internet print-out). It is noted that the claims state that the composition *optionally* includes an olive kernel extract. Thus, this rejection could have been formulated without this reference.

Weiner et al. (US 2002/0009448 A1) disclosed that interferon-β was a known anti-inflammatory cytokine (see [0010]).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried

detergents were held to be *prima facie* obvious.).

In the Instant case, all of the above-listed ingredients were known anti-inflammatory agents. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in treating any inflammatory condition including brain inflammation in multiple sclerosis patients.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in claim 42, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal

concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

*This reference is cited merely to relay an endogenous property of olive kernel and is not used as a basis for rejection *per se*.

Applicant's arguments are solely directed toward the contention that this application now claims priority on earlier pending patent applications due to the filing of a Petition to perfect priority on 2/13/09. However, said petition was Dismissed on 9/21/2009 and therefore Applicant's arguments are not persuasive. All of the documents used in the rejections above are prior art.

If the Examiner can be of any further help in clearing up any priority issues, Applicant is asked to contact the Examiner at the phone number provided below.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit 1655

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